



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,138	10/15/2003	Brian J. Brown	S13.12-0145	6236
38356 7590 07/09/2007 BROOKS, CAMERON & HUEBSCH, PLLC 1221 NICOLLET AVENUE, SUITE 500 MINNEAPOLIS, MN 55403			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 07/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,138

Applicant(s)

BROWN ET AL.

Examiner

Melanie Tyson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-19 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-19, and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 May 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 6, 13, 14, 16, 17, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Case et al. (Publication No. 2004/0167619 A1). Case et al. disclose a device (Figure 15) comprising a generally tubular structure (80) formed of a material substantially invisible under MRI visualization (paragraph 38), a cell (82) defining a portion of a peripheral circumference of the tubular structure (80), and a RF marker (77) including a plurality of windings of conductive material (a radiopaque wire that rings the edges of the cell, paragraph 52) that defines a perimeter, or delineates a

Art Unit: 3731

circumference of the cell (82). Case et al. further disclose inserting the device into a body cavity and exposing the medical device to a magnetic field generated by an MRI system (paragraph 38). Since the marker is used to visually detect the device under MRI (paragraph 38), it is inherent that the clinician is visually detecting changes in anatomic spins due to the RF energy emitted.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Case et al. in view of Tiefenbrun et al. (Patent No. 5,425,765). Case et al. disclose a device as described above, however, fail to disclose the cell is interconnected to additional cells by connectors. Tiefenbrun et al. disclose a device (Figure 1) comprising cells (24, 26, 28, 30) that are interconnected by connectors (strut portions of wire mesh 22). It would have been obvious to one of ordinary skill in the art at the time the

Art Unit: 3731

invention was made to construct the device of Case et al. with cells interconnected by connectors as taught by Tiefenbrun in order to provide a single device capable of bypassing an entire damaged region without blocking other blood vessel junctions (column 1, lines 17-23 and 40-51).

7. Claims 7-9 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Case et al. In addition to the structure described above, Case et al. further teach alternate embodiments in which the peripheral circumference of the tubular structure (80) includes two or more cells that may include the RF marker as described above (paragraph 52), and also teach the RF markers may be embedded in the device (paragraph 42). Since the markers are visible under MRI, it is obvious that the markers are oriented relative to one another to generate RF energy under magnetic fields applied in different directions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device with two or more cells and/or an RF marker that is embedded in itself in order to better adapt the marker for the device (paragraph 42) and to be able to utilize the device in an area of the body that contains multiple branches (paragraph 52).

8. Claims 12, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Case et al. in view of Jackson et al. Case et al. disclose a device as described above, however, fail to disclose a magnetic susceptibility marker connected to the generally tubular structure. Jackson et al. disclose a tubular structure (Figure 3). Jackson et al. teach connecting magnetic susceptibility markers (such as paramagnetic materials; paragraph 16) that are visible under MRI to the tubular structure. It would

have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Case et al. with a magnetic susceptibility marker as taught by Jackson et al. in order to clearly recognize the position of the device under MRI (paragraph 16), thus facilitating proper implantation. Furthermore, since the magnetic marker is used to visually detect the device under MRI (paragraph 38), it is obvious that the user is visually detecting changes in atomic spins due to the magnetic marker.

Response to Arguments

9. Applicant's arguments filed 16 May 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art utilized does not teach all the elements and limitations in the claims. Examiner respectfully disagrees.

Applicant argues that the Case reference does not teach a medical device having a generally tubular structure formed of material *substantially invisible* under magnetic resonance imaging (MRI) visualization. Although Case discloses that most prosthetic devices include a frame or structure that is *somewhat visible* under at least one external imaging method, Case does not teach that the prosthesis is *specifically designed* to be seen under methods such as fluoroscopy, x-ray, ultrasound, M.R.I., etc., as Applicant argues. Contrary to Applicant's interpretation, Case states, in paragraph 38 (cited in previous office action), "For definition purposes, the prosthesis of the present invention comprises a general structure or configuration that would not ordinarily include imageable features related to its primary function that would otherwise allow reliable identification of its orientation under external imaging without the incorporation of the supplemental imageable structure or elements of the present invention that correspond

Art Unit: 3731

to a function of the device.” Therefore, it appears that Case teaches a prosthesis that is *substantially invisible* under MRI, in that the prosthesis offers little or no visual guidance under MRI to aid in aligning the device within the body without the incorporation of imageable elements.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
June 26, 2007

MT

Jackie
(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER

7/5/07